EFFICACY REVIEW

Confidential Business Information (CBI) is discussed in this review. Do not disclose CBI to third parties or to anyone lacking appropriate clearances.

Product(s): Purina Assault W.R. Weather Resistant Poison Bait Block

Date: September 30, 2005

EPA Reg No(s): 67517-76

DP Bar code(s): D287930

Chemical Code: Bromethalin 112802

Formulation(s): Bromethalin Baits (Pellets)

Purpose for Review: The purpose for this review is to determine if the previously submitted efficacy tests dated August 13, 1990, October 8, 1992, and November 3, 1992, are acceptable for reregistration of the above named product.

MRID No(s):

416968-02C Dickerson, C. W. August 13, 1990. Contains 0.01% Bromethalin: N-Methyl 1-2,4-Dinitro-N-(2, 4, 6-Tribromophenyl)-6-(Triflouoromethyl) Benzenamine - Efficacy Data. Water Resistant Block Rodenticide Bait. Experiment #62-774. Purina Mills, Inc. Unpublished Report. OPP Designation 96-12. 55pp.

416968-03C Dickerson, C. W. August 13, 1990. Contains 0.01% Bromethalin: N-Methyl 1-2,4-Dinitro-N-(2, 4, 6-Tribromophenyl)-6-(Triflouoromethyl) Benzenamine - Efficacy Data. Water Resistant Block Rodenticide Bait. Experiment #62-775. Purina Mills, Inc. Unpublished Report. OPP Designation 96-12. 59pp.

426061-01C Dickerson, C. W. October 8, 1992. Testing of a Water Resistant Block Rodenticide in Wild House Mice. - Efficacy Data. Experiment #62-872. Purina Mills, Inc. Unpublished Report. OPP Designation 1.214. 83pp.

426061-02C Dickerson, C. W. October 8, 1992. Testing of a Water Resistant Block Rodenticide in Wild House Mice. - Efficacy Data. Experiment #62-873. Purina Mills, Inc. Unpublished Report. OPP Designation 1.214. 87pp.

426061-03C Dickerson, C. W. November 3, 1992. Testing of a Water Resistant Block Rodenticide in Wild House Mice. - Efficacy Data. Experiment #62-885. Purina Mills, Inc. Unpublished Report. OPP Designation 1.214. 84pp.

426061-04C Dickerson, C. W. November 3, 1992. Testing of a Water Resistant Block Rodenticide in Wild House Mice. - Efficacy Data. Experiment #62-886. Purina Mills, Inc. Unpublished Report. OPP Designation 1.214. 86pp.

Good Laboratory Practices: Yes

Branch Chief: Meredith Laws

Team Leader: John Hebert, Product Manager 07

IRB Reviewer: Geraldine R. McCann, Biologist

BACKGROUND: The original application for the registration of 67517-76 (602-343) is dated 10/21/91. This is a 0.01% Bromethalin bait block proposed for reregistration with a label from April 09, 2002, to control house mice, Norway rats, and roof rats "…inside and against outside walls of homes, industrial and agricultural buildings, and similar man-made structures...alleys located in urban areas, inside transport vehicles (ships, trains, aircraft), and inside and against outside walls of related port or terminal buildings." This product is not to be used in sewers or placed near or inside ventilation duct openings, and this bait is not to be broadcast. The formulation for (the above mentioned) product contains [redacted] to humans and has been widely promoted as a protective adulterant for use in toxic substances. The above six studies have been previously submitted to support the registration of this product. See the jacket and B. Jacobs reviews dated 3/27/91, 9/27/91, 3/4/93, and 6/1/93, for details.

Purina used EPA laboratory efficacy protocol OPP guideline 1.214 (for mice), for all six of the above studies. The bait exposure period was 3 days in all the efficacy studies for this product. Purina used individually caged mice for all tests rather than unisex groupings of 5 or 10 mice each (as stated in OPP Designation 1.210). This procedure is acceptable. The data indicate that the performance criterion of 90% mortality was met or exceeded in all tests (Table 1) except the last one (MRID 426061-04). In this study, the three male mice that survived collectively ate more than all of the group of males collectively. In a letter to R. Forrest from Purina dated March 23, 1993, R. Boyles states: "We have no scientific explanation for the survival of the three males. Occasionally, some will survive, which may be due to genetics, or a lack of a specific enzyme like what occurs in the Guinea Pig."

Review of Data
DISCUSSION:

MRID ‘s 416968-02 and 416968-03 were submitted with the original submission dated November 9, 1990, and rejected by B. Jacobs in his review dated March 27, 1991, for the following reasons: “These tests cannot be accepted until the issues of food containers and bait – weathering procedures are resolved.”

The information for the above two MRID’s (416968-02 and 416968-03) was submitted (July 18, 1991) to satisfy B. Jacobs rejection and he stated in his review dated September 27, 1991: “The procedures used for weathering bait appear to have been appropriate. The pictures of the equipment used to present bait and challenge diet to rats in the efficacy studies previously submitted for this product suggest that the toxic bait might have been somewhat more accessible than the challenge diet to the rats. If such were the case, the extremely high bait acceptance figures reported in the tests might have been due wholly or in part to container-introduced bias. We realize however, that it is difficult to present meal challenge diet and block bait absolutely identically and that attempt to do so run risks of introducing biases of their own. Consequently, we will accept the studies previously submitted as adequate to support the claims made for this product under a condition of registration . We reserve the option to revisit this issue at reregistration or at any time if we receive information which suggests:

a.) that the studies previously submitted were seriously biased in favor of the bait, and

b.) that there are procedures which, if followed, clearly would lead to testing that was far less biased.”

No such information has come to our attention at this time.

In his review of MRID 426061-01, 426061-02, 426061-03, and 426061-04 dated June 1, 1993, B. Jacobs concluded that:

“The information provide on March 23, May 6, and May 12, 1993, concerning the weathering of bait used in the two house mouse studies which you (Purina) submitted on December 18,1992, was helpful in telling us what procedures you followed in weathering baits and in using weathered baits in subsequent efficacy studies. It had not occurred to us prior to these recent discussions and submission(s) that this product is actually subpackaged in plastic cups. As the product has passed weather-resistance tests, at least when in plastic cups, we can accept the claim ‘weather-resistant’ if that the ‘DIRECTIONS FOR USE’ on the label require that the bait be applied in the cups.”

The results of the studies submitted to support this product have been tabularized below:

Table 1. Results of the Studies submitted to support Purina Assault W.R. Weather Resistant Poison Bait Block (67517-76) for Reregistration.

Test MRID Numbers	Subject #s	Sex (Species)	Toxic Bait Eaten (g)	OPP Diet Eaten (g)	Bait Acceptance Rate (%)	Mortality Results (%)	Days to Death (Day 1/Day 2)
416968-02** 62-774	20	B (Mice)	158.3	39.3	80.1	100	1-3 * (3/16)
416968-03** 62-775	20	B (Mice)	160.6	67.3	70.5	100	1-8 * (4/13)
426061-01 62-872	20	B (Mice)	26.2	15.1	63.4	100	1-3 (2/16)
426061-02 62-873	20	B (Mice)	20.7	31.0	40.0	100	1-9 (3/8)
426061-03** 62-885	20	B (Mice)	27.1	44.3	38.0	100	2-6 (0/9)
426061-04** 62-886	20	B (Mice)	49.4	74.4	39.9	80.0 ***	2-5 (0/11)

* Females were consistent and all but one died on Day 2, one died on Day 1.

** Weathered bait tests

*** The explanation for the 80% is due to the survival of four males that ate from 0.00 g to 12.3 g (For the explanation, see the Background notes)

Conclusion(s) The efficacy reports submitted for this product reregistration have been found acceptable. I agree the W. Jacobs conclusions from his March 4, 1993, review (67517-76) that: "The two house mouse efficacy studies in which it appears that fresh bait was used are acceptable (426061-01 and 426061-02)." data submitted to support the claims made for the weatherability of this product in the packaged cups are acceptable.